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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,242	11/09/2001	Michelle Lu	680.0043USU	9256

7590 07/15/2003

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,242

Applicant(s)

LU ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 11,12 and 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 6. 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' supplemental IDS, filed 04/14/2003; and election, filed 04/28/2003.

Response to Election/Restrictions

1. Applicant's election of Group I, claims 1-10 and 13-18 in Paper No. 7 is acknowledged. Although applicants stated that the election is made with traverse, but applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 11, 12, 19-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II and III.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-10 and 13-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the instant claimed invention is composition comprising substantially undifferentiated plant seed cells and pharmaceutically or cosmetically acceptable vehicles; and method of improving the aesthetic appearance of skin comprising topically applying a composition having substantially undifferentiated plant seed cells and pharmaceutically or cosmetically acceptable vehicles. Nowhere in the specification applicants teach how the plant seed cells are kept in a viable undifferentiated state till they reach the customer, especially in the various claimed vehicles of claim 9, such as alcohols, that may be detrimental to the undifferentiated cells. The specification does not show how the undifferentiated plant seed cells are kept in the undifferentiated state in the culture media without progression of the developmental process towards the differentiation of the cells because once the

cells start to differentiate they will continue as long as they are in the suitable culture media till full differentiation of different parts of the plants is achieved. The specification is unenabling regarding how the culture media would be incorporated in the composition of the present invention because in the instant specification second paragraph of page 5, applicants disclosed that the culturing can be carried out by adding whole seeds or portions thereof to the nutrient medium, and in page 7, third paragraph, they disclosed that the whole nutrient medium is admixed in the cosmetically acceptable vehicle, and that means if the whole seeds are present in the culture media, then the composition will have seeds admixed in the vehicle providing coarse composition. Claim 10 recites the composition is in a product selected from aerosol spray, cream, dispersion, foam, gel, lotion, mousse, ointment, powder, patch, pomade, solution, pump spray, stick and towelette, and it is not clear from the specification how the undifferentiated plant seed cells will be incorporated in the above products and stayed in the viable undifferentiated condition in the above products and how the whole seed in the culture could be present in any of the above products.

The breadth of the claims: The claims are very broad. The claims encompass a wide class of plant seed cells and culture media. The claims language includes even the whole seed because the cells are not isolated. In page 5, second paragraph of the specification, applicants teach culturing whole seeds, or portions thereof.

The state of the prior art: The state of the art does not recognize the incorporation of the plant seed cells in a pharmaceutical or cosmetic composition and method of its use to improve the aesthetic appearance of the skin, but the art

Art Unit: 1615

recognized the use of the plant seed extract in pharmaceutical composition to treat dermatological disorders, as in WO 00/64472, abstract, page 11, lines 3-10, 20-25; page 12, lines 1-15; page 25, lines 26-30.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on the incorporation of the culture comprising plant seed cells into a cosmetic or pharmaceutical composition while the cells of the plant seeds are kept in a viable undifferentiated condition till they reach the customer. No guidance from the present disclosure regarding the condition in which the culture contain whole seeds, how this could be incorporated in the composition, some seeds are huge, as coconut claimed in claim 8, and the claim language does not exclude the whole seed.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to using undifferentiated plant seed cells in their culture in a composition, wherein the seeds could be whole seeds, makes practicing the claimed invention unpredictable in the terms of using undifferentiated seed cells.

The presence or absence of working examples: The specification discloses culturing whole seeds or portions thereof, page 5, and incorporation of the culture media as a whole into the composition, page 7. No working examples to show how the culture media incorporating the seeds or seed cells would be admixed into the composition to provide a cosmetic or pharmaceutical composition in the various products claimed in claim 10.

The quantity of experimentation necessary: The art demonstrates using a plant seed extract. Therefore, the practitioner would turn to trial and error experimentation to practice the instant composition without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

For examination purposes, and since the seed cells are not isolated cells, the claims read on seeds cultured in water, because seed cells are undifferentiated cells and water is an acceptable vehicle.

5. Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improving the aesthetic appearance of the skin, page 10, last paragraph, does not reasonably provide enablement for preventing loss of collagen and elastin, preventing skin atrophy, preventing the wrinkles, preventing hyperpigmentation, preventing skin sagging, preventing loss of glycosaminoglycans, or preventing cellulite formation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of *In re Wands* factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability of the art, the working examples, and the amount of

experimentation necessary. All the factors have been considered with regard to the claim, with the most relevant factors discussed below.

The nature of the invention: The rejected claims are drawn to the methods of improving the aesthetic appearance of the skin, i.e. the skin is already compromised, wherein the improvements include preventing loss of collagen and elastin, preventing skin atrophy, preventing the wrinkles, preventing hyperpigmentation, preventing skin sagging, preventing loss of glycosaminoglycans, or preventing cellulite formation with the administration of the instant composition. The nature of the invention is extremely complex in that it encompasses multiple complex skin conditions having unrelated manifestations and subsequently prevented by administering the instant composition comprising substantially undifferentiated plant seed cells.

The breadth of the claims: The complex nature of the claims is exacerbated by the breadth of the claims. The claim encompasses prevention of complex conditions that may have potential causes other than those disclosed in the specification. This may or may not be addressed by the administration of the claimed composition. Moreover, the specification is directed to skin conditions caused by aging, see page 10 of the specification. However, numerous other skin conditions, such as discoloration, signs of fatigue and skin barrier repair, are encompassed by the instant claims

The state of the art: The state of the art does not recognize the administration of compositions to prevent the skin conditions as required in the instant claims. The state of the art recognizes the treatment of the symptoms of these skin conditions but not their cure, WO 00/64472.

The guidance of the specification: The guidance given by the specification on how to prevent the skin conditions is absent. Guidance for improving the aesthetic appearance of skin is provided, no evidence that these conditions are prevented is provided.

The predictability of the art: The lack of significant guidance from the specification or prior art with regard to completely preventing loss of collagen and elastin, preventing skin atrophy, preventing the wrinkles, preventing hyperpigmentation, preventing skin sagging, preventing loss of glycosaminoglycans, or preventing cellulite formation with the administration of the instant composition comprising undifferentiated plant seed cells makes practicing the claimed invention unpredictable in terms of the prevention of these conditions.

The presence or absence of working examples: The specification discloses improving the aesthetic appearance of the skin, no working examples to show preventing loss of collagen and elastin, preventing skin atrophy, preventing the wrinkles, preventing hyperpigmentation, preventing skin sagging, preventing loss of glycosaminoglycans, or preventing cellulite formation by administering the instant composition.

The amount of experimentation necessary: The art demonstrates treatment of skin aging symptoms, but does not teach prevention of these conditions. Therefore, the practitioner would turn to trial and error experimentation to make/use the instant compositions for preventing loss of collagen and elastin, preventing skin atrophy, preventing the wrinkles, preventing hyperpigmentation, preventing skin sagging,

Art Unit: 1615

preventing loss of glycosaminoglycans, or preventing cellulite formation, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

For examination purposes, the phrase “preventing” is interpreted as “treating” the instant conditions.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 6, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,698,423 ('423).

Claim 1 reads on seeds in water, because the cells of the seeds are not differentiated yet, and water is an acceptable vehicle. The claim language does not exclude the whole seeds, as it is not directed to isolated cells. The preamble “topical” does not limit the scope of the claim because it does not provide antecedent basis for the terms in the body of the claim, and the body of the claim sets out the complete invention, i.e. the composition itself, and further the permeable merely provides statement for the intended use and not essential to understand the terms in the body of the claim. Thus, the term “topical” reads on any surface.

Art Unit: 1615

US '423 disclosed a plant cell culture comprises cells from *Azadirachta indica* (neem) in an aqueous solution, wherein the cultured cells can be obtained from the seeds and they are undifferentiated, which reads on claim 1 and 6, and reads also on the products of claim 10 since the seed cells are in a solution, which is one of the products claimed in claim 10 (col.4, lines 37-38, 53-55; col.7, lines 23, 33-35). The culture allows continuous production of the useful bioactive products from the cells at a desired location (surface) and yields a predictable quantity and quality of bioactive product (abstract; col.5, lines 42-52). Example 1 shows neem seeds cultured in water, which reads on the vehicle claimed in claim 9.

Thus, the reference disclosure reads on a composition comprising undifferentiated neem seed cells in a vehicle (water), and meets the limitations of claims 1, 6, 9, and 10.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1615

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2-5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '423.

The teachings of US '423 is discussed above, however the reference does not teach the amount of the plant seed cells in the composition as claimed in claims 2-5, 7.

The prior art recognized yielding of a predictable quantity of the bioactive product by the continuous production of useful bioactive products from the cultured plant seed cells at a desired location. Therefore, according to the intended use and the site of application, one having ordinary skill in the art would manipulate the amount of the cultured seed cells in the composition in order to achieve a beneficial effect, and the claimed amounts do not impart patentability to a composition comprising undifferentiated plant seed cells, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the composition comprising undifferentiated plant seed cells in a culture as disclosed by US '423, and to select the amount of the cultured seed to be incorporated in the composition depending on the intended use because the reference teaches that the culture allows continuous production of the useful bioactive products from the cells at a desired location and yields a predictable quantity and quality

Art Unit: 1615

of bioactive product, with reasonable expectation of having a composition providing the bioactive products from the cultured plant seed cells in a continuous manner at the desired amount to a particular location or site of application with success.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

